REMARKS/ARGUMENTS

I. Status of the Claims

Claim 18 has been canceled. Claim 11 has been amended to delete the reference to "external aggression or combinations thereof" and to incorporate the limitations of claim 18. Accordingly, no new matter has been introduced by this Amendment.

Applicants submit that the amendment to the claims does not introduce new matter and is fully supported by the specification and claims, as originally filed. Applicants request the Examiner to enter the amendment because the amendments to the claims either cancel claims, comply with requirements of form expressly set forth in a previous Office Action, or present the rejected claims in better form for consideration on appeal.

II. Rejections Under 35 U.S.C. § 112

a. First Paragraph

The Examiner has rejected claims 11-22 under 35 U.S.C. § 112, first paragraph. Specifically, the Examiner takes the position that there is no written support in the specification or claims as originally filed for "measuring eicosanoid levels in response to only applying a topical skin care product that generically has an anionic surfactant in it." Applicants respectfully disagree.

The Specification is replete with discussions of a method of measuring the subclinical or clinical inflammation or irritation of mammalian skin due to exposure of topical skin care products by measuring levels of eicosanoid. See, for example, page 5, lines 9-26. Example 2 discloses a topical skin care product which comprises anionic surfactant (SLS) although that specific example does not measure levels of eicosanoid. However, Example 3, measures levels of eicosanoid after exposure to a topical skin care product comprising anionic surfactant, for example, ammonium laureth sulfate. As the Examiner is well aware, there is no in *haec verba* requirement, rather, newly added claim limitations can be supported in the specification through express, implicit or inherent disclosure. See MPEP 2163. Here, the disclosure as a whole, reasonably conveys that the inventor had possession of the subject matter of the amendment, i.e., measuring levels of eicosanoid after exposure to a topical skin care product comprising anionic surfactant, at the time of the filing of the application.

b. Second Paragraph

The Examiner has rejected claims 11-22 under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants have amended claim 11 to delete the reference to "external aggression or combinations thereof." Accordingly, Applicants respectfully request withdrawal of this rejection.

II. Rejections Under 35 U.S.C. 103(a)

A. *The Rejection of Claims 1-6, 8-16 and 18-20 and 22*

The Examiner has rejected claims 11-15 and 17-21 as allegedly unpatentable over Mueller-Decker et al. (reference AH) in view of Perkins et al. (reference AG). Applicants respectfully traverse this rejection.

The Examiner relies upon Meuller-Decker al. as teaching "an invasive method measuring PGE2 levels in skin blister fluid as [a]n indicator of skin irritation that has had SLS applied to it in aqua bidest." The Examiner recognizes that Mueller-Decker et al. fails to teach the use of a non-invasive adhesive coated microporous plastic film to collect the skin secretions. To cure this deficiency, the Examiner relies upon Perkins et al.

Perkins et al. relates to the use of Sebutape® to assess inflammatory changes in human skin by measuring the level of cytokines. There is no teaching or suggestion that Sebutape® could be used to determine the level of eicosanoid. The Examiner takes the position that it would have been obvious at the time the invention was made to substitute suction blister fluid method of measuring cytokines and eicosanoids taught by Reilly et al. with the Sebutape® method taught by Perkins et al. Applicants respectfully disagree.

As the Examiner is well aware, to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See M.P.E.P. § 2143. Here, there is nothing in the teachings of Perkins et al. that would provide one of ordinary skill in the art with the motivation that Sebutape® could be used to measure the level of eicosanoids in human skin. Indeed,

Perkins et al. does not even mention eicosanoids. Further, one of ordinary skill in the art would not reasonable expect that Sebutape could be successfully used to replace the suction blister fluid method taught by Mueller-Decker et al.

It is the Examiner's position that it would have been obvious to substitute the Sebutape™ as taught by Perkins et al. in the Mueller-Decker et al. process for measuring skin inflammation because "Sebutape™ is able to detect molecular mediators of skin irritation without being invasive." However, as mentioned above, there is nothing in the teachings of Perkins et al. that would provide one of ordinary skill in the art with the suggestion that Sebutape™ could be used to could be successfully used to replace the suction blister fluid method taught by Mueller-Decker et al. As mentioned above, Perkins does not even mention the measurement of eicosanoids. Accordingly, Applicants respectfully request withdrawal of this rejection.

Further, as amended the presently claimed invention relates to a method for measuring sub-clinical or clinical inflammation or irritation of mammalian skin from exposure of said skin to a topical skin care product comprising anionic surfactant by measuring levels of eicosanoid and cytokine in secretions collected from the surface of the skin before and after exposure. As discussed in the Specification and demonstrated by Example 2, anionic surfactants may interact with proteins such as IL-1α which would cause denaturation of the proteins which in turn would effect the immunoassay and result in lower apparent levels of IL-1α observed. Applicants claimed method using eicosanoid and cytokines as the inflammation/irritation marker retains stability in the presence of a wide variety of skin care products. None of the references relied upon by the Examiner, taken alone or in any combination, teach or suggest a method for measuring sub-clinical or clinical inflammation or irritation of mammalian skin from exposure of said skin to a topical skin care product comprising anionic surfactant. Accordingly, Applicants respectfully request withdrawal of this rejection.

B. *The Rejection of Claims 11, 16 and 22*

The Examiner has rejected claims 11, 16 and 22 as allegedly unpatentable in view of Mueller-Decker and Perkins et al. and further in view of Reilly et al. This rejection is traversed at least for the reasons discussed above with respect to the combination of Mueller-Decker and

Perkins et al. and for the additional limitations present in claims 16 and 22. Specifically, Reilly et al. does not cure the deficiencies of Mueller-Decker and Perkins et al.

VI. Conclusion

Applicants believe that the foregoing presents a full and complete response to the outstanding Office Action. An early and favorable response to this Amendment is earnestly solicited. If the Examiner feels that a discussion with Applicants' representative would be helpful in resolving the outstanding issues, the Examiner is invited to contact Applicants' representative at the number provided below.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/JBP0581USNP/EMH. If a fee is required for an Extension of time 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

By /Erin M. Harriman/
Erin M. Harriman
Reg. No. 40,410

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3619

Dated: August 17, 2006